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## (12) United States Patent

## Buan et al.

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## (54) METHOD FOR PROVIDING A NEGATIVE PRESSURE WOUND THERAPY PUMP DEVICE

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## (56) References Cited

### U.S. PATENT DOCUMENTS

695,270 A	3/1902	Beringer
1.480,562 A	1/1924	Mock
2,280,915 A	4/1942	Johnson
2,367,690 A	1/1945	Purdy
2,568,933 A	9/1951	Robbins
2,632,443 A	3/1953	Lesher
2,682,873 A	7/1954	Evans et al.
3,367,332 A	2/1968	Groves
3,486,504 A	12/1969	Austin et al.
	(Con	tinued)

#### FOREIGN PATENT DOCUMENTS

CA	2198243 A1	2/1996
CA	2367460 A1	10/2000
	(Cont	inued)

### OTHER PUBLICATIONS

U.S. Appl. No. 60/559,727, filed Apr. 5, 2004, Richard Scott Weston. (Continued)

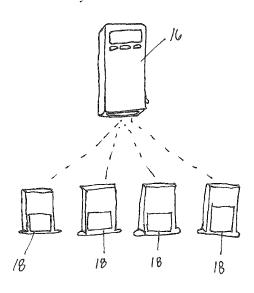
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## (57) ABSTRACT

A method for providing a device used in association with a negative pressure wound therapy bandage wherein a controller module and a plurality of pump modules are provided to a third party, who leases the controller module and provides the pump modules to an end user. A case for the device may also be provided.

## 9 Claims, 4 Drawing Sheets



# US 9,058,634 B2 Page 2

(56)	Ref	eren	ces Cited	6,135,116 D434,150			Vogel et al. Tumey et al.
	U.S. PATE	ENT	DOCUMENTS	6,142,982		11/2000	Hunt et al.
				6,168,800			Dobos et al.
3,572,340			Lloyd et al.	6,176,307 6,225,523		1/2001 5/2001	Danos et al.
3,610,238 3,874,387			Rich et al. Barbieri	6,254,567			Treu et al.
3,993,080			Loseff	6,255,552	B1	7/2001	Cummings et al.
4,102,342	A 7/1		Akiyama et al.	6,261,283			Morgan et al.
4,112,947			Nehring	6,287,521 6,345,623			Quay et al. Heaton et al.
4,136,696 4,184,510			Nehring Murry et al.	6,398,767			Fleischmann
4,217,894	A 8/1		Franetzki	6,402,724			Smith et al.
4,219,019			Coates	6,450,773 6,458,109		9/2002	Upton Henley et al.
4,224,945 4,250,882			Cohen Adair	6,465,708			Augustine
4,316,466			Babb	6,471,685		10/2002	
4,382,441			Svedman	6,471,982 6,482,491			Lydon et al. Samuelsen et al.
4,465,485 4,468,227			Kashmer et al. Jensen	6,491,684			Joshi et al.
4,525,166			Leclerc	6,553,998			Heaton et al.
4,534,356			Papadakis	6,599,262 6,648,862		7/2003 11/2003	
4,551,141 4,573,965			McNeil Russo	6,673,028	B1		Argenta et al.
4,608,041			Nielsen	6,676,610	B2	1/2004	Morton et al.
4,655,766		987	Theeuwes et al.	6,685,681			Lockwood et al.
4,681,562			Beck et al.	6,695,823 6,695,824			Lina et al. Howard et al.
4,710,165 4,778,446			McNeil et al. Jensen	6,752,794	B2	6/2004	Lockwood et al.
4,778,456	A 10/1	988	Lokken	6,755,807			Risk, Jr. et al.
4,792,328			Beck et al.	6,764,462 6,767,334			Risk, Jr. et al. Randolph
4,795,435 4,820,284			Steer Hauri	6,814,079			Heaton et al.
4,921,488			Maitz et al.	6,824,533	B2		Risk, Jr. et al.
4,936,834			Beck et al.	6,855,135 6,856,821			Lockwood et al. Johnson
4,950,483 4,969,880			Ksander et al. Zamierowski	6,936,037		8/2005	
4,972,829			Knerr	6,951,553	B2		Bubb et al.
4,979,944	A 12/1		Luzsicza	6,977,323			Swenson Bybordi et al.
4,994,022 5,055,198			Steffler et al. Shettigar	6,979,324 6,994,702			Johnson
5,056,510			Gilman	7,004,915	B2	2/2006	Boynton et al.
5,073,172	A 12/1	991	Fell	7,022,113			Lockwood
5,100,396 5,149,331			Zamierowski Ferdman et al.	7,067,709 7,070,584			Murata et al. Johnson et al.
5,152,757			Eriksson	7,077,832	B2	7/2006	Fleischmann
5,167,613	A 12/1	992	Karami et al.	7,087,806			Scheinberg et al.
5,176,663			Svedman et al.	7,108,683 7,118,545		10/2006	Zamierowski Boyde
5,215,519 5,261,893		993 993	Shettigar Zamierowski	7,128,735	B2	10/2006	Weston
5,266,928			Johnson	7,195,624			Lockwood
5,279,608		994	Cherif Cheikh	7,214,202 7,216,651		5/2007	Vogel et al. Argenta et al.
5,328,614 5,358,494			Matsumura Svedman	7,361,184	B2	4/2008	
5,380,280			Peterson	7,381,859			Hunt et al.
5,437,651			Todd et al.	7,438,705 7,494,482			Karpowicz et al. Orgill et al.
5,445,604 5,489,280			Lang Russell	7,503,910		3/2009	Adahan
5,498,338			Kruger et al.	7,524,315			Blott et al.
5,527,293			Zamierowski	7,534,240 7,534,927		5/2009	Johnson Lockwood
5,549,584 5,562,107			Gross Lavender et al.	7,569,742			Haggstrom
5,636,643		997	Argenta et al.	7,611,500			Lina et al.
5,643,189		997	Masini	7,612,247 7,615,036		11/2009 11/2009	Oyaski Joshi
5,645,081 5,678,564		997 997	Argenta et al. Lawrence et al.	7,645,253			Gura et al.
5,733,337			Carr et al.	7,645,269			Zamierowski
5,759,570	A 6/1	998	Arnold	7,678,090 7,699,823			Risk, Jr. Haggstrom
5,785,688 5,830,496		998 998	Joshi et al. Freeman	7,699,823		4/2010	
5,833,646			Masini	7,708,724		5/2010	
5,843,011	A 12/1	998	Lucas	7,717,313			Criscuolo et al.
5,857,502		999	Buchalter	7,753,894 7,759,537			Blott et al. Bishop et al.
5,868,933 5,876,611		999 999	Patrick et al. Shettigar	7,759,537			Fleischmann
5,964,723			Augustine	7,759,539			Shaw et al.
6,071,267	A 6/2	000	Zamierowski	7,763,000			Risk, Jr.
6,103,951			Freeman	7,775,998			Riesinger
6,110,197	A 8/2	UUU	Augustine et al.	7,776,028	<b>B</b> 2	8/2010	Miller et al.

## US 9,058,634 B2

Page 3

(56)	Referen	ces Cited	2005/0020955			Sanders et al.
U.S	PATENT	DOCUMENTS	2005/0028828 2005/0058694			Heaton et al. Nielsen
0.0		DOCOMENTO	2005/0070835		3/2005	
7,779,625 B2	8/2010	Joshi	2005/0080372			Nielsen et al.
7,790,945 B1		Watson, Jr.	2005/0090787 2005/0148913			Risk, Jr. et al. Weston
7,790,946 B2 7,794,438 B2		Mulligan Henley	2005/0148513			Miller et al.
7,794,438 B2 7,794,450 B2		Blott et al.	2005/0261643		11/2005	
7,811,269 B2		Boynton	2006/0015087		1/2006	
7,815,616 B2		Boehringer et al.	2006/0025727			Boehringer et al.
7,825,289 B2	11/2010		2006/0029650 2006/0041247			Coffey Petrosenko et al.
7,828,782 B2 7,838,717 B2	11/2010	Haggstrom	2006/0069365			Sperl et al.
7,846,141 B2	12/2010		2006/0079852	Al		Bubb et al.
7,862,339 B2		Mulligan	2006/0100586			Karpowicz et al.
7,883,494 B2	2/2011		2006/0100594 2006/0116620			Adams et al. Oyaski
7,909,805 B2 7,959,624 B2		Weston Riesinger	2006/0110020			Lockwood
7,959,024 B2 7,964,766 B2		Blott et al.	2006/0149170			Boynton et al.
7,976,519 B2		Bubb et al.	2007/0005028			Risk, Jr.
7,998,125 B2		Weston	2007/0010797			Nishtala et al.
8,062,272 B2	11/2011		2007/0038172 2007/0055209			Zamierowski Patel et al.
8,062,273 B2 8,080,702 B2	11/2011	Blott et al.	2007/0141128			Blott et al.
8,100,887 B2		Weston	2007/0167884			Mangrum et al.
8,105,295 B2		Blott et al.	2007/0179460			Adahan
8,118,794 B2		Weston	2007/0185426 2007/0185463		8/2007 8/2007	Ambrosio et al. Mulligan
8,128,615 B2	3/2012 4/2012		2007/0183403			Karpowicz et al.
8,152,785 B2 8,162,907 B2		Heagle	2007/0265585		11/2007	Joshi et al.
8,162,909 B2		Blott et al.	2007/0265586		11/2007	Joshi
8,235,955 B2		Blott et al.	2008/0004549			Anderson
8,641,693 B2		Locke et al.	2008/0004559 2008/0039759			Riesinger Holm et al.
2001/0016205 A1 2001/0029956 A1		Shimizu Argenta	2008/0077091		3/2008	Mulligan
2001/0029930 A1 2001/0034499 A1		Sessions et al.	2008/0082059		4/2008	Fink
2002/0065494 A1		Lockwood et al.	2008/0108977			Heaton et al.
2002/0068913 A1		Fleischmann	2008/0119802 2008/0167593			Riesinger Fleischmann
2002/0115952 A1 2002/0120185 A1	8/2002	Tumey Johnson	2008/0107393		7/2008	
2002/0120185 A1 2002/0143286 A1	10/2002		2008/0188820		8/2008	
2002/0150720 A1		Howard et al.	2008/0208147			Argenta et al.
2002/0161346 A1		Lockwood et al.	2008/0223378			Henderson et al.
2002/0183702 A1		Henley et al.	2008/0306407 2008/0306456			Taylor Riesinger
2002/0198503 A1 2002/0198504 A1		Risk et al. Risk et al.	2009/0005746		1/2009	
2003/0014022 A1		Lockwood et al.	2009/0036873		2/2009	
2003/0014025 A1		Allen et al.	2009/0054855		2/2009 2/2009	Blott et al.
2003/0021775 A1		Freeman	2009/0054856 2009/0069759			Mormino et al. Blott et al.
2003/0040687 A1 2003/0050594 A1		Boynton et al. Zamierowski	2009/0125004		5/2009	Shen
2003/0088202 A1		Gilman	2009/0131888		5/2009	
2003/0097086 A1	5/2003	Gura	2009/0177135			Rogers et al.
2003/0108587 A1		Orgill et al.	2009/0192499 2009/0198201			Weston et al. Adahan
2003/0125649 A1 2003/0144619 A1		McIntosh Augustine	2009/0138201			Robinson et al.
2003/0171675 A1		Rosenberg	2009/0221977	Al	9/2009	Blott et al.
2003/0175798 A1		Raees et al.	2009/0227968		9/2009	
2003/0208149 A1	11/2003		2009/0227969 2009/0234306		9/2009 9/2009	
2003/0212357 A1	11/2003		2009/0234300		9/2009	
2003/0212431 A1 2003/0225347 A1		Brady et al. Argenta et al.	2009/0234309			Vitaris et al.
2004/0019342 A1		Nagasuna et al.	2009/0240185		9/2009	
2004/0030304 A1		Hunt et al.	2009/0240218			Braga et al.
2004/0039391 A1		Argenta et al.	2009/0254053 2009/0254054		10/2009	Svensby Blott et al.
2004/0039415 A1 2004/0054338 A1		Zamierowski Bybordi et al.	2009/0264837		10/2009	Adahan
2004/0054538 AT 2004/0064132 AT		Boehringer et al.	2009/0270820	A1	10/2009	Johnson
2004/0122434 A1	6/2004	Argenta et al.	2009/0299251		12/2009	
2004/0127834 A1	7/2004		2009/0299255			Kazala, Jr. et al.
2004/0127862 A1 2004/0127863 A1		Bubb et al. Bubb et al.	2009/0299256 2009/0299257			Barta et al. Long et al.
2004/0127803 AT 2004/0167482 AT		Watson	2009/0299237		12/2009	
2004/0107402 A1		Johnson	2009/0299307			Barta et al.
2004/0241214 A1		Kirkwood et al.	2009/0299341	A1	12/2009	Kazala, Jr. et al.
2004/0249353 A1	12/2004		2009/0299342		12/2009	Cavanaugh, II et al.
2005/0004534 A1		Lockwood et al.	2009/0306580		12/2009	Blott et al.
2005/0010153 A1	1/2005	Lockwood et al.	2009/0312723	ΑI	12/2009	Blott et al.

(56) <b>Ref</b> e	erences Cited		DE	4 012 232	10/1991
II C DATE	ENT DOCUMENTS		DE EP	198 44 355 0 020 662	4/2000 7/1984
0.3.1A11	ENT DOCUMENTS		EP	0 355 186	2/1990
2009/0312728 A1 12/20	009 Randolph et al.		EP	0 777 504	10/1998
	009 Vitaris		EP EP	0 782 421 1 897 569	7/1999 8/2002
	010 Augustine et al. 010 Heagle et al.		EP	0 708 620	5/2003
	010 Rrohn		EP	1 088 569	8/2003
2010/0042074 A1 2/2	010 Weston		EP EP	1 440 667	3/2006
	010 Adahan		EP EP	1 284 777 1 171 065	4/2006 3/2007
	010 Heagle 010 Olson		EP	1 476 217	3/2008
	010 Olson		EP	1 121 163	11/2008
	010 McNeil		EP FR	2098257 A 1163907	.1 9/2009 10/1958
	010 Joshi et al. 010 Weston et al.		GB	114754	4/1918
	010 Weston et al.		GB	641061	8/1950
2010/0121286 A1 5/26	010 Locke et al.		GB	1224009 A	
	010 Vrzalik et al.		GB GB	1549756 A 2195255 A	
	010 Coulthard et al. 010 Bernstein		GB	2378392 A	
	010 Weston		GB	2415908 A	
	010 Heagle		JP SU	2003-165843	6/2003
	010 Pidgeon 010 Blott et al.		WO	1251912 A WO 84/01904	.1 4/1983 5/1984
	010 Buan et al.		WO	WO 90/11795	10/1990
2010/0274207 A1 10/2	010 Weston		WO	WO 91/00718	1/1991
	010 Gordon		WO WO	WO 92/20299 WO 96/05873	11/1992 2/1996
	010 Haggstrom et al. 010 Watson, Jr.		wo	WO 99/01173	1/1999
	010 Watson, 31.		WO	WO 00/07653	2/2000
2010/0298866 A1 11/2	010 Fischvogt		WO	WO 00/50143 A	
	010 Coulthard		WO WO	WO 00/59424 WO 01/19430 A	10/2000 .1 3/2001
	010 Vess et al. 010 Witt	705/2	wo	WO 01/34223	5/2001
	010 Malhi et al.	705,2	WO	WO 01/037922	5/2001
	010 Andresen et al.		WO WO	WO 01/85248 WO 01/93793	11/2001 12/2001
	010 Braga et al. 010 Patel et al.		WO	WO 02/083046 A	
	010 Fatel et al. 011 Eckstein et al.		WO	WO 02/092783	11/2002
2011/0009835 A1 1/2	011 Blott		WO	WO 03/045492	6/2003
	011 Svedman		WO WO	WO 03/057307 WO 03/092620	7/2003 11/2003
	011 Hartwell 011 Hartwell		WO	WO 2004/024300	3/2004
	011 Buan		WO	WO 2004/037334	5/2004
	011 Haggstrom		WO WO	WO 2005/025666 WO 2005/051461	3/2005 6/2005
	011 Hartwell 011 Locke et al.		wo	WO 2005/031401 WO 2005/070480	8/2005
	011 Blott et al.		WO	WO 2005/082435	9/2005
	011 Blott		WO WO	WO 2007/024230 WO 2007/030601	3/2007 3/2007
	011 Weston		WO	WO2007024230	3/2007
	011 Weston 011 Wilkes et al.		WO	WO 2009/066105	5/2009
	011 Jacobs		WO	WO 2009/066106	5/2009
	011 Hu et al.		WO	WO 2012/022484	2/2012
	011 Scholz			OTHER P	PUBLICATIONS
	011 Bharti et al. 011 Weston		II.O	1 11 60/572 655	C1 1 1 M 21 2004 B' 1 1 G W
	011 Weston 011 Topaz				filed May 21, 2004, Richard Scott
	011 Greener et al.		Weston		led Oct. 6, 2006, Blott et al.
	011 Coulthard et al.				led Aug. 14, 2008, Hartwell et al.
	011 Blott et al.			11	led Nov. 2, 2011, Adie et al.
	011 Adie et al. 012 Blott et al.				led Nov. 2, 2011, Allen et al.
	012 Blott et al.				ctive dressings and serum proteins: an
	012 Weston			•	nd Care, February, vol. 5, No. 2, 1996
2014/0121617 A1 5/20	014 Locke et al.		(pp. 79		ıum-Assisted Closure: A New Method
FOREIGN PA	ATENT DOCUMENTS		ment; Clinical Experience", Ann Plas		
CA 2390513	A1 5/2001		Aubre	y, D.A., et al., Treat	ment of the Perineal Wound after
CA 2121688					rrigation, Arch. Surg., Oct. 1984, 119,
CA 2408305	A1 11/2001		1141-1		of External Vacuum Assisting is the
CA 2458285 CA 2157772					of External Vacuum Aspiration in the s of Soft Tissues," in current Problems
DE 2809828	9/1978				nterdepartmental Collection, edited by
DE 3 935 818	5/1991			~ .	a State University, Cheboksary, USSR

## (56) References Cited

## OTHER PUBLICATIONS

1986) pp. 94-96 (with English translation).

Biblehimer, Helen L., "Dealing With a Wound that Drains 1.5 Liters a Day," RN, Aug. 1986, pp. 21-23, USA.

Bier, A., Hyperemia as a Therapeutic Agent, Ed. Dr. Gustavus M. Blech, A. Robertson & Co., Chicago 1905, pp. 74-85.

Brubacher, "To Heal a Draining Wound", RN Mar. 1982, 7 pages. Bucalo et al. "Inhibition of Cell Proliferation by Chronic Wound Fluid." Wound Repair and Regeneration, Miami, 1993, pp. 181-186. Canadian Office Action for Canadian Application No. 2739605 dated Aug. 22, 2011 in 2 pages.

Chariker, M.E., et al, "Effective Management of Incisional and Cutaneous Fistulae with Closed Suction Wound Drainage," Contemporary Surgery. Jun. 1989, pp. 59-63, vol. 34 USA.

Chinese Office Action dated Aug. 29, 2008 for Patent Application No. 200480032101.1.

Chintamani, et al., "Half versus full vacuum suction drainage after modified radical mastectomy for breast cancer—a prospective randomized clinical trial", Research Article (Jan. 27, 2005), 1-5.

Costunchenok, BM, Effect of Vacuum on Surgical Purulent Wounds, Vestnik Chirurgia, 1986, 6 pages.

Davydov et al. "Pathogenic Mechanisms of the Effect of Vacuum Therapy on the Course of the Wound Process" pp. 43-46 (Dec. 1990). Davydov, Yu A., et al., "Concepts for Clinical Biological Management of the Wound Process in the Treatment of Purulent Wounds Using Vacuum Therapy", The Kremlin Papers: Perspectives in Wound Care, Russian Journal: Vestnik Khirurgii, BlueSky Publishing, La Costa, California (2004), 15-17.

Davydov, Yu A., et al., "The Bacteriological and Cytological Assessment of Vacuum Therapy of Purulent Wounds", The Kremlin Papers: Perspectives in Wound Care, Russian Journal: Vestnik Khirurgii, BlueSky Publishing, La Costa, California (2004), 11-14.

Davydov, Yu A., et al., "Vacuum Therapy in the Treatment of Purulent Lactation Mastitis", The Kremlin Papers: Perspectives in Wound Care, Russian Journal: Vestnik Khirurgii, BlueSky Publishing, La Costa, California (2004), 5-7.

De Lange, M.Y., et al., "Vacuum-Assisted Closure: Indications and Clinical Experience", Eur J Plast Surg (2000) 2;178-182 (Feb. 9, 2000).

Dilmaghani et al., "A Method for Closed Irrigation and Suction Therapy in Deep Wound Infections," Journal of Bone and Joint Surgery, 1969, vol. 51-A, No. 2, pp. 323-342.

EPO, Office Action for EP App. No. 04791592.1 dated Jun. 12, 2008. EPO, Second European Office Action for EP App. No. 04791592.1 dated Feb. 10, 2011.

Fleischmann, Vacuum sealing: indication, technique, and results, European Journal of Orthopaedic Surgery & Traumatology (1995), pp. 37-40.

Fleischmann, W. Wund Forum Spezial. IHW '94. "Vakuumversiegelung zur Behandlung von Problemwuden" (with English translation: Vacuum Sealing for Treatment of Problematical Wounds).

Garcia-Rinaldi, R., et al., Improving the Efficiency of Wound Drainage Catheters, Amer. Journ. of Surg., Sep. 1975, pp. 130, 372-373. Hartz, R.S., et al., Healing of the Perineal Wound, Arch. Surg., Apr. 1980, 115, 471-474.

Health Technology, Literature R., "Vacuum Assisted Closure Therapy for Wound Care", Health Technology Literature Review (Dec. 2004), 3-59.

International Preliminary Report for International Application No. PCT/GB/2004/004549, dated Dec. 20, 2005.

International Search Report for International Application No. PCT/GB/2004/004549, dated Feb. 21, 2005.

Japanese Office Action dated Aug. 25, 2009 for Patent Application No. 2006-537411.

Japanese Office Action dated Dec. 15, 2009 for Patent Application No. 2006-537411.

Japanese Office Action dated Jun. 22, 2010 for Patent Application No. 2006-537411.

Japanese Office Action dated Jan. 17, 2012 for Patent Application No. 2010-59188.

Jeter, K.F., et al, "Managing Draining Wounds and Fistulae: New and Established Methods", Chronic Wound Care, pp. 240-246.

Johnson, F.E., An Improved Technique for Skin Graft Placement using a Suction Drain, Surgery, Gynecology and Obstetrics, Dec. 1984. 3 pages.

KCI Inc., If It's Not VAC Therapy, It's Not Negative Pressure Wound Therapy, Jan. 2005.

Khirugii, Vestnik, "A Collection of Published Studies Complementing the Research and Innovation of Wound Care", The Kremlin Papers, Perspectives in Wound Care, Russian Medical Journal, Vestnik Khirugii, Blue Sky Publishing (2004), 2-17.

Kostiuchenok, B. M., et al., "The Vacuum Effect in the Surgical Treatment of Purulent Wounds", The Kremlin Papers: Perspectives in Wound Care, Russian Journal: Vestnik Khirurgii, BlueSky Publishing, La Costa, California (2004), 3-4.

Landes, R.R. and I. Melnick, An Improved Suction Device for Draining Wounds, Arch. Surg., May 1972, 104, p. 707.

Linden, Willem van der, et al, "Randomized Trial of Drainage After Cholecystectomy: Suction Versus Static Drainage Through a Main Wound Versus a Stab Incision", American Journal of Surgery, Feb. 1981, vol. 141, pp. 289-294.

Mcfarlane, R.M., The Use of Continuous Suction under Skin Flaps, Br. Journ. Plast. Surg., pp. 77-86.

Mclaughlan, J, et al, "Sterile Microenvironment for Postoperative Wound Care", The Lancet, Sep. 2, 1978, pp. 503-504.

Meyer, W. and V. Schmeiden, Bier's Hyperemic Treatment, Published 1908 W. B. Saunders Company, pp. 44-65.

Morykwas, Michael J., et al., "Vacuum-Assisted Closure: A New Method for Wound Control and Treatment: Animal Studies and Basic Foundation", Ann Plast Surg 1997;38:553-562 (Dec. 10, 1996).

Nakayama, Y, et al, "A New Method for the Dressing of Free Skin Grafts", Plastic and Reconstructive Surgery, Dec. 1990 pp. 1216-1219. UK.

Nursing 75, Wound Suction: Better Drainage with Fewer Problems, Nursing, vol. 5, No. 10, Oct. 1975, pp. 52-55.

Office Action (Final) for U.S. Appl. No. 10/575,875, published as 2007/129,707, dated Jun. 17, 2009 in 19 pages.

Ramirez, O.M., et al., Optimal Wound Healing under Op-Site Dressing, Ideas and Innovations, 73(3), pp. 474-475.

Ranson, J. H. C., et al, "Safer Intraperitoneal Sump Drainage", Surgery, Gynecology & Obstetrics, Nov. 1973, vol. 137, pp. 841-842. Sames, C.P., Sealing of Wounds with Vacuum Drainage, Br. Med.

Journ., Nov. 5, 1977, p. 1223, Correspondence. Solovev, V. A., et al., "The Method of Treatment of Immature External Fistulas in the Upper Gastrointestinal Tract—Guidelines" USSR Ministry of Health, S. M. Kirov Gorky State Medical Institute, 1987 (with English translation).

Solovey, V.A. "Treatment and Prevention of Suture Failures after Gastric Resection" (Dissertation Abstract) (S.M. Kirov Gorky State Medical Institute, Gorky USSR 1988).

Stewart, Joanne, Ph.D., World Wide Wounds—Next generation of products for wound management—2002 (13 pages).

Svedman, P., "Irrigation Treatment in Split-Thickness Skin Grafting of Intractable Leg Ulcers," Scand J. Plast. Reconst. Surg., 19:211-213, 1985.

Svedman, P., "Irrigation Treatment of Leg Ulcers," The Lancet, Sep. 1983, 532-34.

Svedman, P., A Dressing Allowing Continuous Treatment of a Biosurface, IRCS Med. Science: Biomed. Tech.; Clinic. Med.; Surg. and Transplantation, 1979, 7, p. 221.

Svedman, P., et al., "A Dressing System Providing Fluid Supply and Suction Drainage Used for Continuous or Intermittent irrigation," Annals of Plastic Surgery, vol. 17, No. 2, Aug. 1986, pp. 125-133.

Swift, et al, "Quorum Sensing in *Aeromonas hydrophila* and *Aeromonas salmoncida*: Identification of LuxRl Homologs AhyRl and AsaRl and Their Cognate N-Acylhomoserine Lactone Signal Molecules," J. Bacteriol., 179(17):5271-5281 (1997).

Teder and Svedman et al., "Continuous Wound Irrigation in the Pig," Journal of Investigative Surgery, 1990, vol. 3, pp. 399-407.

## (56) References Cited

## OTHER PUBLICATIONS

Tribble, David E. M.D., An Improved Sump Drain-Irrigation Device of Simple Construction, Archives of Surgery New York, pp. 511-513, 1972 vol. 105.

Usupov, Y. N., et al., "Active Wound Drainage", The Kremlin Papers: Perspectives in Wound Care, Russian Journal: Vestnik Khirurgii, BlueSky Publishing, La Costa, California (2004), 8-10.

Venturi, Mark L., "Mechanisms and Clinical Applications of the Vacuum-Assisted Closure (VAC) Device", Am J Clin Dermatol (2005) 693, 185-194; Review Article (2005), 185-194.

Vijanto, J. and J. Raekallio, Local Hyperalimentation of Open Wounds, Br. J. surg., 1976, 63, 427-430.

Wackenfors, A., et al., Effects of Vacuum-Assisted Closure Therapy on Inguinal Wound Edge Microvascular Blood Flow, *Wound Rep. Reg*, 2004, 12, 600-606.

Webb, New Techniques in Wound Management: Vacuum-Assisted Wound Closure, Journal of the American Academy of Orthopaedic Surgeons, v. 10, No. 5, pp. 303-311, Sep. 2002.

Webster's Revised Unabridged Dictionary, published 1913 by C. & G. Merriam Co., definition of Flapper Valve, downloaded from Free Online Dictionary.

Westaby, S., et al., "A Wound Irrigation Device", The Lancet, Sep. 2, 1978, pp. 503-504.

Wooding-Scott, Margaret, et al., "No Wound is Too Big for Resourceful Nurses," RN Dec. 1988, pp. 22-25 USA.

Wound Suction, Nursing, Oct. 1975, USA pp. 52-53.

Wu, W.S., et al. Vacuum therapy as an intermediate phase in would closure: a clinical experience, Eur J Plast Surg (2000) 23: pp. 174-177.

US 6,306,115, 10/2001, Kelly et al. (withdrawn)

\* cited by examiner

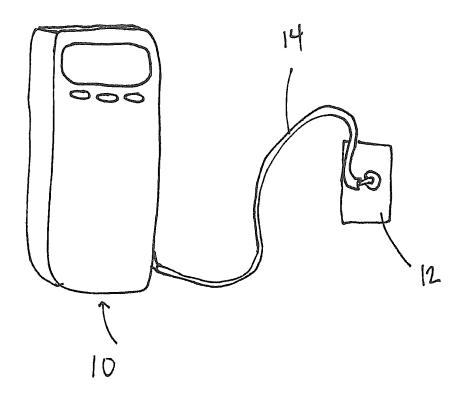
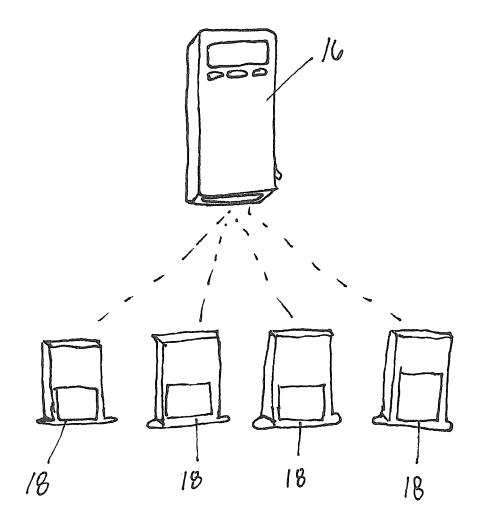
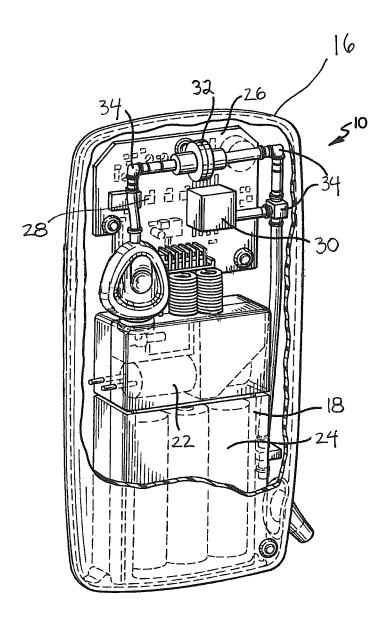


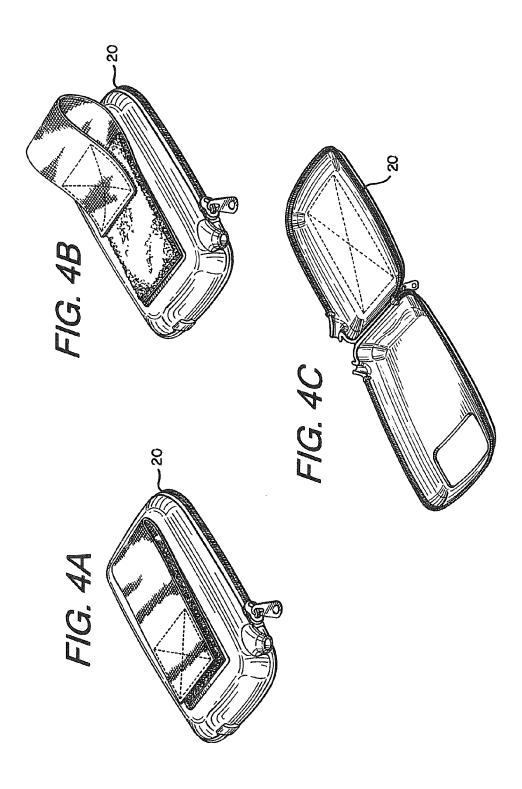
FIG. 1



F16. 2



F16.3



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# METHOD FOR PROVIDING A NEGATIVE PRESSURE WOUND THERAPY PUMP DEVICE

## CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Patent Application No. 61/489,310 filed on May 24, 2011, the entirety of which is incorporated by reference.

## FIELD OF THE INVENTION

The invention relates to a method for providing/supplying a pump system for negative pressure wound therapy.

## BACKGROUND OF THE INVENTION

Negative pressure wound therapy (NPWT) is one method of treating certain wounds or sores on people. In general, a 20 specialty dressing (or bandage) is placed over a wound site, and connected to a pump system. The pump system provides suction, creating a negative pressure under the bandage at the wound site. Exudates and other materials are removed from the wound site under the influence of the negative pressure. 25 The NPWT wound dressings are single patient use and purchased as needed.

The pump systems, which at retail purchase are quite expensive, are generally leased from a medical device supply company (DME) to an "end user" for the period of time <sup>30</sup> necessary to heal the chronic wound, typically 6-8 weeks. The "end-user" can either be a patient, whose insurance carrier makes the lease payments, or a "facility," such as a nursing home or hospital, which will lease the equipment on behalf of the patient. Given the relatively short term of use for any one <sup>35</sup> patient, it does not make any financial sense for either a patient or a treating facility to own such equipment.

The pumping devices are designed to be durable and capable of being reused across the care of multiple patients. However, being complex electromechanical systems, they 40 can break down or otherwise fail, requiring both the end users and the leasing company to maintain a sufficient level of inventory. This can be both costly and require a large amount of space for both the leasing company and the end users.

Moreover, given that the structural component of the system that performs the actual pumping of air, the pump, is believed to be the most likely element to fail in the pumping system, it would be beneficial for all interested parties, DME and end-users, to be able to employ a system that minimizes the cost associated with repairing and using these NPWT pumping systems, and otherwise avoid disposing of the functioning elements in the pumping device.

The present invention is directed to resolving these and other matters.

## SUMMARY OF THE INVENTION

In one embodiment of the invention, the invention is directed towards a method for providing a device to be used in association with a negative pressure wound therapy bandage 60 including the steps of providing a controller module including a pressure sensor to a third party, providing a first pump module including a pump to the third party, providing a second pump module including a second pump to the third party, wherein the third party leases the controller module to an end 65 user, and, wherein the controller module removably receives the first pump module and provides a first negative pressure

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treatment, and wherein after providing the first negative pressure treatment, the first pump module can be removed and the second pump module can be inserted into the controller module for providing a second negative pressure treatment.

In an embodiment of the invention, the controller module, first pump module and second pump module are provided simultaneously. As used herein "simultaneously" is intended to mean in the same transaction, and, preferably in the same shipment or package.

In a further embodiment, a first case sized to cover the controller module and the first pump module received therein is provided and a second case sized to cover the controller module and the second pump module received therein is also provided. These may be provided simultaneously with each other, and may also be provided simultaneously with the pump modules.

Yet another embodiment of the invention includes providing a third pump module including a third pump to the third party, and, providing a fourth pump module including a fourth pump to the third party. The can be provided simultaneously with the controller module, first pump module and second pump module. These can also be provided in association with cases, which may be provided simultaneously with the pump modules and/or the controller module.

In still another embodiment of the present invention, the invention is directed to a method for providing a device to be used in association with a negative pressure wound therapy bandage by leasing a controller module including a pressure sensor to an end user, providing a first pump module including a pump to the end user, providing a second pump module including a second pump to the end user, wherein the end user utilizes the controller module and the first pump module to provide a first negative pressure treatment, wherein the controller module removably receives the first pump module, and wherein after providing the first negative pressure treatment, the first pump module can be removed and the second pump module can be inserted into the controller module for providing a second negative pressure treatment.

As in other embodiments, cases may be provided with the pump modules. Further, the cases, pump modules and/or controller modules may be leased and/or provided simultaneously. In addition, additional pump modules may also be provided.

Further, it is contemplated that in any of these embodiments, one or more negative pressure wound therapy bandages are provided to the third party in connection with the other devices.

One of ordinary skill in the art will appreciate that while the embodiments discusses providing a single controller module and various numbers of pump modules, the invention encompasses providing any number of controller modules and pump modules to the purchaser/end user.

A method according to one or more embodiments of the present invention is believed to provide numerous benefits.

One or more of the disclosed embodiments, would allow the end users that lease the controller units to have a large supply replaceable pump modules. If the pump module fails before, during, or after negative pressure wound therapy treatment, the end user can simply obtain another pump module its own inventory, switch out the pump modules, and begin/ resume a second negative pressure wound therapy treatment.

These methods would also benefit the individuals (people, companies, etc.) that supply the pump devices to the end users because they could also create a large inventory of pump modules to provide/sell to the end users. At the same time, they do not need to maintain such a large inventory of controller modules that are being leased to cover broken or oth-

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erwise non-functioning pump devices. In other words, with other systems, these suppliers would need enough of an inventory to cover a certain number of pump devices breaking down in the field. However, with one or more of the embodiments of the present invention, the supplies could minimize the amount of controller modules in inventory, and build up a larger supply of pump modules.

Further, since the suppliers do not have to build such a large supply of controller modules, the suppliers can minimize their financial investment in a non-used inventory. In other words, the suppliers do not have to spend as much money on controller modules for inventory.

Since the controller modules are intended to be used with different patients at different times, it is beneficial to provide disposable covers to minimize the spread of diseases, bodily fluids and otherwise promote general cleanliness in the health care environment.

It is to be understood that the aspects and objects of the present invention described above may be combinable and that other advantages and aspects of the present invention will become apparent upon reading the following description of the drawings and detailed description of the invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will become more fully apparent from the following description and appended claims, taken in conjunction with the accompanying drawings. Understanding that the accompanying drawings depict only typical embodiments, and are, therefore, not to be considered to be 30 limiting of the scope of the present disclosure, the embodiments will be described and explained with specificity and detail in reference to the accompanying drawings as provided below

FIG. 1 is a front perspective view of a device provided 35 according to one or more embodiments of the present invention

FIG. 2 is a front perspective view exploded view of a controller module and a plurality of pump modules provided according to one or more embodiments of the present invention.

FIG. 3 is a front side cutaway view of a device provided according to one or more embodiments of the present invention.

FIGS. **4***a-c* are a top view of a cover provided according to 45 one or more embodiments of the present invention.

## DETAILED DESCRIPTION OF THE DRAWINGS

While this invention is susceptible of embodiment in many 50 different forms, there is shown in the drawings and will herein be described in detail one or more embodiments with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the embodiments illustrated.

Reference throughout this description to features, advantages, objects or similar language does not imply that all of the features and advantages that may be realized with the present invention should be or are in any single embodiment 60 of the invention. Rather, language referring to the features and advantages is understood to mean that a specific feature, advantage, or characteristic described in connection with an embodiment is included in at least one embodiment of the present invention. Thus, discussion of the features and advantages, and similar language, throughout this specification may, but do not necessarily, refer to the same embodiment.

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In reference to the attached drawings, the present invention is directed towards a method of providing a device 10 used in association with a negative pressure wound therapy bandage 12. Typically, tubing 14 is utilized to provide negative pressure from the device 10 to the negative pressure wound therapy bandage 12.

Certain embodiments of the invention include the steps of providing a controller module 16, and providing a plurality of pump modules 18. The pump modules 18 contain a pump 22, and preferably a power source 24. The controller module 16 may contain, inter alia, electronics 26, LEDs 28, a pressure sensor 30, a check valve 32, and tubing 34.

The controller module 16 and pump modules 18 are typically sold to a third party; however, the present invention contemplates that they may be leased, rented, lent, or provided free as a demo. As used herein "third party" means a company, person or other entity that does not manufacture the devices 10, controller modules 16 or pump modules 18 and that does not administer or otherwise perform negative pressure wound therapy treatment. However, the present invention contemplates that the manufacturer of the devices 10, controller modules 16 or pump modules 18 may be the lessor of the controller module 16.

The third party then leases the controller module 16 to an end user. As used herein, "end user" means a company, person or other entity that administers or otherwise performs negative pressure wound therapy treatment on a patient. The third party also provides pump modules 18 to the end user. Since the pump modules 18 are meant to be disposed, this transaction may be a lease, it may be a sale, or they may be provided free. Alternatively, different number of pump modules 18 may be provided under different transaction conditions. For example, the first pump module 18 with each controller module 16 may be provided free, and additional pump modules 18 may be sold, leased, rented, lent, etc.

After the end user performs negative pressure wound therapy on a patient, or if the first pump module 18 fails, the end user can switch out the first pump module 18 for a second pump module 18. After the second pump module 18 is used on a patient, the end user can switch out the second pump module 18 for a third, and so on and so forth. This allows the end user, and the third party, to build up a supply of pump modules 18, which are relatively inexpensive, while maintaining a smaller supply of controller modules 16, which are relatively expensive.

In certain embodiments, at least one of the pump modules 18 may be provided simultaneously with the controller modules 16. As will be appreciated, after the initial transaction, subsequent pump modules 18 may be provided after the controller module 16 has been provided.

Moreover, certain embodiments include providing a disposable case 20, sized to cover the device 10. It is contemplated that a cover 20 is provided with each pump module 18 so as to maintain a level of cleanliness, since the controller module 16 is intended to be used with different patients, while the pump modules 18 are intended to be disposed of after one use.

As discussed above, a method according to one or more embodiments of the present invention is believed to provide a number of advantageous and benefits in the field of providing negative pressure wound therapy.

It is to be understood that additional embodiments of the present invention described herein may be contemplated by one of ordinary skill in the art and that the scope of the present invention is not limited to the embodiments disclosed. While specific embodiments of the present invention have been illustrated and described, numerous modifications come to

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mind without significantly departing from the spirit of the invention, and the scope of protection is only limited by the scope of the accompanying claims.

What is claimed is:

1. A method for providing a device to be used in association with a negative pressure wound therapy bandage, comprising the steps of:

providing a controller module including a pressure sensor to a third party:

- providing a first pump module to the third party, the first pump module comprising a first pump and a first power source:
- providing a second pump module to the third party, the second pump module comprising a second pump and a 15 second power source;
- providing a third pump module to the third party, the third pump module comprising a third pump and a third power source;
- providing a fourth pump module to the third party, the fourth pump module comprising a fourth pump and a fourth power source;
- wherein the third party leases the controller module to an end user; and,
- wherein the controller module removably receives the first pump module and provides a first negative pressure treatment, and wherein after providing the first negative pressure treatment, the first pump module can be removed and the second pump module can be inserted into the controller module for providing a second negative pressure treatment.
- 2. The method of claim 1, wherein the controller module, first pump module and second pump module are provided simultaneously.
  - 3. The method of claim 1, further comprising the steps of: providing a first case sized to cover the controller module and the first pump module received therein; and,
  - providing a second case sized to cover the controller module and the second pump module received therein.
- **4**. The method of claim **1**, wherein the first pump module, the second pump module, the third pump module and the fourth pump module are provided simultaneously.

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- 5. The method of claim 4, further comprising the step of: providing a case with each pump module sized to cover the controller module and each pump module received therein.
- **6**. The method of claim **5**, wherein the cases are provided simultaneously with the pump modules.
- 7. A method for providing a device to be used in association with a negative pressure wound therapy bandage, comprising the steps of:
  - leasing a controller module including a pressure sensor to an end user;
  - providing a first pump module to the end user, the first pump module comprising a first pump and a first power source:
  - providing a second pump module to the end user, the second pump module comprising a second pump and a second power source;
  - providing a third pump module to the end user, the third pump module comprising a third pump and a third power source:
  - providing a fourth pump module to the end user, the fourth pump module comprising a fourth pump and a fourth power source;
  - wherein the controller module removably receives the first pump module;
  - wherein the end user utilizes the controller module and the first pump module to provide a first negative pressure treatment; and
  - wherein after providing the first negative pressure treatment, the first pump module can be removed and the second pump module can be inserted into the controller module for providing a second negative pressure treat-
- **8**. The method of claim **7** wherein the controller module, first pump module and second pump module are provided simultaneously.
  - 9. The method of claim 7, further comprising the steps of: providing a first case sized to cover the controller module and the first pump module received therein; and,
  - providing a second case sized to cover the controller module and the second pump module received therein.

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